Phenol, 2-nitro-: Human health tier II assessment

12 December 2019

CAS Number: 88-75-5

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

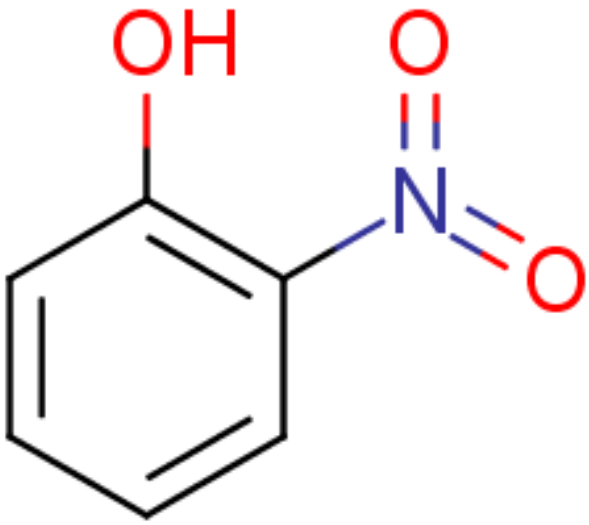
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	o-nitrophenol o-hydroxynitrobenzene
Structural Formula	
Molecular Formula	C6H5NO3
Molecular Weight (g/mol)	139.6
Appearance and Odour (where available)	light yellow needles or prisms, peculiar aromatic odour
SMILES	c1(O)c(N(=O)=O)cccc1

Import, Manufacture and Use

Australian

The chemical 2-nitrophenol is not included in the list of chemicals used in permanent and semi-permanent hair dyes in Australia (NICNASa, 2007). No other use, import, or manufacturing information was available.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of chemicals (REACH), European Commission Cosmetic Ingredients and Substances (CosIng) database; Galleria Chemica; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); the US Agency for Toxic Substances and Disease Registry (ATSDR) and the World Health Organisation (WHO) Concise International Chemical Assessment Document (CICAD) 20 (WHO, 2000).

The chemical 2-nitrophenol is reported to have a cosmetic use in hair dyeing or as a hair colourant (CosIng; INCI). However, there is currently no documented use of the chemical in cosmetic products on the US market (CIUCUS, 2011; Environmental Working Group (EWG) Skin Deep Cosmetics Database; US HPD).

No domestic uses have been identified for the chemical.

The chemical is reported to have site-limited use in the synthesis of dye intermediates, rubber, fungicides, lumber preservatives, medicinal products, paint colourings and photographic chemicals.

It is also reported to be used as an additive in tobacco products.

The chemical 2-nitrophenol is on the OECD List of High Production Volume (HPV) Chemicals. Historical data indicate that the production volume of Western Europe was estimated at 6400 t for 2-nitrophenol in 1983 and between 1–9 million pounds in the USA in 1989 (CICAD, 2000; ATSDR, 1999).

Restrictions

Australian

2-Nitrophenol is listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 6 under the entry for NITROPHENOLS (SUSMP, 2019).

Schedule 6:

'NITROPHENOLS, ortho, meta and para, **except** when separately specified in these Schedules.'

Schedule 6 chemicals are labelled 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label (SUSMP, 2019).

International

No specific international restrictions were identified for the chemical.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards have been reported for 2-nitrophenol—exposure limit of 3 mg/m^3 time weighted average (TWA) and short-term exposure limit (STEL) of 6 mg/m^3 in Russia (RTECS).

Health Hazard Information

In literature, the 3 structural isomers of nitrophenol (ortho, meta and para) are often collectively referred to as mononitrophenols or nitrophenols. It appears that the toxicity of nitrophenols as a collective group was determined primarily from the data available on the para and ortho isomers. The animal data for 2-nitrophenol (ortho-nitrophenol) are poorly described and often do not follow OECD test guidelines. They indicate low irritation potential whereas 4-nitrophenol (para-nitrophenol) is classified as hazardous, causing serious eye damage and skin irritation (NICNASa). While the proximity of the nitro group to the hydroxyl group could lead to hydrogen bonding and a corresponding reduction in activity of the nitro group and reduced acidity, the two isomers have similar dissociation constants. Thus, the properties of the better characterised isomer 4-nitrophenol can be read across to 2-nitrophenol when evaluating irritation potential. Further, there are human data on unspecified nitrophenols, which are assumed to be a mixture of these two isomers, that indicate that the mixture is highly irritating to humans (HSDBa). In the absence of more reliable data for 2-nitrophenol, it is safer to conclude that the properties for mixed nitrophenols apply to this chemical.

Nitrophenols are reported to interfere with normal metabolism by uncoupling oxidative phosphorylation (HSDBa).

Toxicokinetics

Mononitrophenols are readily absorbed into the body by ingestion, inhalation of aerosols and through the skin. Animal studies showed that all 3 structural isomers are rapidly metabolised and excreted following similar metabolic pathways of conjugation and to a lesser extent reduction. A study in rabbits found that 2-nitrophenol mainly undergoes phase II conjugation at the hydroxyl group to form water-soluble conjugates, which can easily be filtered out by the kidneys. Regardless of the route of exposure, bioaccumulation is not expected for any of the isomers as any absorbed chemical is rapidly metabolised and excreted (CICAD, 2000; HSDBa).

In rabbits given a single dose of 2-nitrophenol in doses ranging from 200–330 mg/kg bw via gavage, most of the applied dose (80 %) was excreted in the urine within 24 h. About 71 % was conjugated with glucuronic acid and about 11 % with sulfate, while about 3 % was reduced to aminophenols (CICAD, 2000).

In vitro studies show that dermal absorption of the chemical occurs through simple diffusion (CICAD, 2000; REACH).

Acute Toxicity

Oral

The chemical 2-nitrophenol has low toxicity based on results from animal tests following oral exposure. The median lethal dose (LD50) in rats is ≥3100 mg/kg. Reported signs of toxicity include reduced appetite and activity, weakness, collapse, acute gastrointestinal inflammation and haemorrhagic areas of lungs (REACH).

In an acute oral toxicity study similar to OECD Test Guideline (TG) 401, rats (strain unspecified, 10/sex/dose) were administered 2-nitrophenol with 14 days observation. The LD50 was reported to be >3200 mg/kg bw (REACH).

In an acute oral toxicity study in Sprague Dawley (SD) rats (5/sex/dose), the chemical was administered by gavage and the LD50 was reported to be 3100 mg/kg bw. Sublethal effects included reduced appetite and activity, weakness, collapse, acute gastrointestinal inflammation and haemorrhagic areas of lungs (REACH).

Acute oral toxicity LD50 values for 2-nitrophenol were reported in rodent studies with limited information: 2830–4930 mg/kg bw (rats) and 2080–2920 mg/kg bw (mice). Two of the studies reported lower values: 336 mg/kg bw (rats) and 1300 mg/kg bw (mice) (REACH; ASTDR, 1999; CICAD, 2000).

Exposure to nitrophenols is associated with a risk of elevated levels of methaemoglobin in the blood (see **Acute toxicity: Observation in humans** section). In cats (2/group, no controls), oral administration of 2-nitrophenol at 50, 100, and 250 mg/kg bw resulted in a dose-dependent increase in methaemoglobin (6, 44 and 57 % respectively). One animal dosed at 250 mg/kg bw died (CICAD, 2000).

Dermal

The chemical 2-nitrophenol has low toxicity based on reported results from studies with limited details in rats and rabbits following dermal exposure. The LD50 was >2000 mg/kg bw in rats and >7940 mg/kg bw in rabbits. Reported signs of sublethal toxicity included decreased appetite and activity in rabbits (REACH).

In an acute dermal toxicity study in New Zealand White (NZW) rabbits, 40 % 2-nitrophenol in corn oil was administered under semi-occlusive conditions with a 14 day observation period. Reduced appetite and activity were observed for 2–3 days. There were no deaths and the viscera appeared normal at sacrifice. The LD50 was reported to be >7940 mg/kg bw.

Two studies in rats with limited information reported LD50 values of >2000 mg/kg bw and >5000 mg/kg bw (REACH; CICAD, 2000).

No formation of methaemoglobin was observed following dermal application to rabbits of a 50 % solution of 2-nitrophenol in water (dose not specified, exposure time 1 minute to 20 hours on the back or 20 hours on the ear) (CICAD, 2000).

Inhalation

No mortality was observed following inhalation exposure at low doses in a non-guideline study with limited details in rats. However, due to the effects seen in humans on inhalation exposure (see **Acute toxicity: Observations in humans** section), acute inhalation toxicity of the chemical cannot be excluded.

In an acute inhalation toxicity study in rats (strain unspecified, 12/sex/dose) rats were exposed to 2-nitrophenol as a saturated vapour for 8 hours. The LC50 value for this exposure period was determined to be >0.22 mg/L. No deaths were reported (REACH; CICAD, 2000).

Observation in humans

Mononitrophenols can be toxic by all routes of exposure—dermal, ocular, oral and inhalation. Acute toxic effects may include severe irritation to skin and eyes; bluish discolouration of the skin; cough and sore throat; vomiting; nausea; drowsiness; abdominal pain; headache; dizziness; shock; convulsions and unconsciousness (HSDBa; HSDBb; CICAD, 2000). Exposure to chemicals in this chemical class (nitrophenols or nitroaromatics) can cause methaemoglobinaemia (a disorder of the blood which results in impaired oxygen transport in the body) (Blanco & Blanco, 2017; CICAD, 2000).

Corrosion / Irritation

Skin Irritation

Although 2-nitrophenol is reported to be a slight irritant in animal studies, classification for irritation is warranted based on skin irritation reported in humans, and in humans and animals for 4-nitrophenol. 4- Nitrophenol is classified as hazardous with hazard category 'Skin irritation – category 2' and hazard statement 'Causes skin irritation' (H315) in the HCIS (NICNASa).

In a non-guideline skin irritation study with limited details, 2-nitrophenol (an 80 % aqueous solution) was administered under occlusion to 2 Vienna white rabbits for 1, 5 and 15 minutes, and 20 hours, with observations at 24 hours and 8 days. Mean scores for erythema were 0, 1, 1 for 5 minutes, 15 minutes and 20 hours exposures, respectively (observed at 24 hours, out of a maximum score of 4). Mean scores for oedema were 0 and 1 for 15 minute and 20 hours, respectively (observed at 24 hours, out of a maximum score of 4). All effects were reversible within 8 days, apart from scaling and erythema following 20 hours exposure (REACH).

The chemical was also found to be slightly irritating in 2 other rabbit studies with limited information (REACH).

Eye Irritation

Although 2-nitrophenol is reported to be a slight irritant in animal studies, classification for eye irritation is warranted based on reported serious eye damage in humans and the available data for 4-nitrophenol, which is classified as hazardous with hazard category 'Eye damage – category 1' and hazard statement 'Causes serious eye damage' (H318) in the HCIS (NICNASa) (see **Recommendation** section).

In an eye irritation study similar to OECD TG 405, 2 NZW rabbits were administered 2-nitrophenol in 1 eye each, the eyes were not washed out and were observed at 1, 24, 48 hours and 8 days. Mean scores for the first animal were: corneal opacity 0.3/4; conjunctival redness 1/3; chemosis 0.3/4. Mean scores for the second animal were: corneal opacity 0.67/4, conjunctival redness 1/3; and chemosis 0.67/4. All effects were reversible (REACH).

The chemical was not found to be irritating in 2 eye irritation studies with limited details in rabbits (REACH).

Observation in humans

Mononitrophenols can cause severe irritation to the skin and eyes (see **Acute toxicity: Observations in humans section).**

The chemical 2-nitrophenol in the form of dust is irritating to the nose and throat in humans (HSDBb).

Sensitisation

Skin Sensitisation

Based on the limited available data, the chemical is not expected to cause skin sensitisation.

In a Buehler test in guinea pigs comparable to OECD TG 406, 2-nitrophenol was not sensitising (CICAD, 2000). No study details were available.

Repeated Dose Toxicity

Oral

Based on the limited available information, 2-nitrophenol is not expected to produce significant toxicity following repeated oral exposure based on studies in rats.

In a subacute oral study similar to OECD TG 407, Wistar rats (5/sex/dose) were administered 2-nitrophenol at 22, 67 and 200 mg/kg bw/day. Higher doses were not administered to avoid crystallisation of the test substance in the stomach. No further information was provided. Food intake decreased in high-dose males and in mid- and high-dose females, and final body weight decreased non-significantly in all treated groups. Absolute liver and kidney weights were decreased in mid-dose animals, and the relative testes weight increased in low- and mid-dose males and decreased in high-dose males. In all treated groups, the relative and absolute weights of the adrenal glands increased. A no observed effects level (NOEL) was not determined (REACH, CICAD 2000).

Chronic exposure to mononitrophenols (isomer unspecified) in mammals produced changes in neurohumoural regulation, inflammation of the gastro-intestinal tract, liver and spleen, and nerve damage (HSDBa).

Dermal

No animal data are available.

Inhalation

Based on a 4 week animal study, the chemical is not expected to produce significant systemic toxicity on repeated exposure by inhalation. However, due to the effects seen in humans on inhalation exposure, toxicity of the chemical following repeated exposures cannot be excluded.

In a subacute inhalation toxicity study, SD rats (15/sex/group) were exposed (whole body) to the vapour of the melted test substance at doses of 5, 30 and 60 mg/m^3 for 6 h/day, 5day/week for 4 weeks. Methaemoglobin values determined after the 11th exposure were significantly increased only in low-dose animals (males: 1.0, 2.3, 1.8, and 1.6 %; females: 2.0, 4.1, 2.1, and 1.1 %), but were within control values at the end of the study. No further details were provided. Based on the changes observed in epithelial tissue, a lowest observed adverse effect level (LOAEL) was set at 0.06 mg/L (REACH).

Observation in humans

Longer term exposure to nitrophenols may lead to cataract formation and growth retardation (HSDBa).

Genotoxicity

Limited data are available for 2-nitrophenol. The overall negative results suggest that the chemical is not likely to be genotoxic.

A small percentage of the 2-nitrophenol is expected to be reduced to 2-aminophenol (CAS No. 95-55-6) (see the **Toxicokinetics** section) which was found to be genotoxic (NICNASb).

The following in vitro data are available (CICAD, 2000; USEPA, 2007; REACH):

- several bacterial reverse mutation assays were reported in *Salmonella typhimurium*. The chemical was not mutagenic in *S. Typhimurium* TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation up to 5 mg/plate;
- the chemical was not mutagenic in a recombination assay with *Bacillus subtilis* H17 or M45 tested at 0.01–0.5 mg/plate*;*
- the chemical did not induce DNA breakage in a λ phage DNA assay using 35 mg; and
- positive results were obtained in an in vitro mammalian chromosome aberration test in Chinese hamster cells (cell type unspecified) with metabolic activation using fluorimetry in a flow cytometer, a protocol that has not been validated. Negative results were found without metabolic activation.

The chemical tested negative for reciprocal translocations in a sex-linked recessive lethal assay (absolute doses not specified) in *Drosophila melanogaster* using feed (400 and 500 ppm) and injection (2500 and 5000 ppm) (NTP).

Carcinogenicity

Limited data are available data.

In a 12-week study, no skin tumours were seen in female Sutter mice following twice weekly dermal applications of 20 % solution of 2- or 4-nitrophenol in dioxane (CICAD, 2000).

Occupational exposure to chemicals similar to nitrophenols is associated with methaemoglobinaemia (HSDBa).

Squamous metaplasia in the maxillo-turbinates and nasoturbunates were also reported in a subacute toxicity study in rats following inhalation exposure to 2-nitrophenol at 0.06 mg/L (see **Repeat dose toxicity: Inhalation** section).

Reproductive and Developmental Toxicity

Based on available data, 2-nitrophenol is not expected to have any specific reproductive or developmental toxicity. Treatment with the chemical did not result in specific developmental toxicity in a range-finding developmental toxicity study in rats except at doses resulting in maternal toxicity (CICAD, 2000; REACH).

Reproductive toxicity

No reproductive toxicity studies were available.

Changes were observed in relative testes weight in a 28-day study in rats following repeated oral exposure to the chemical but the effects were not dose-related (see **Repeat dose toxicity: Oral** section).

Developmental toxicity

Treatment with the chemical did not result in specific developmental toxicity except at doses resulting in maternal toxicity.

In a range-finding developmental toxicity study in Charles River COBS CD rats (5/group), 2-nitrophenol was administered to pregnant rats at 50, 125, 250, 500 or 1000 mg/kg bw/day via gavage from gestation days (GD) 6–15. Uterine contents were examined on GD 20. The 2 highest doses caused signs of maternal toxicity (transient but dose-related decrease in weight gain early during treatment). One high-dose animal died of unknown causes. Other clinical findings included changes in urine colour and staining of fur. At the highest dose, slight but statistically significant increases in group mean post-implantation losses and mean early resorptions was seen. No other effects were observed. The foetuses were not examined for malformations. The LOAEL was 1000 mg/kg bw/day based on increased post-implantation losses and early resorptions (CICAD, 2000; REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are local effects—serious eye damage and skin irritation.

Although limited data did not allow for definite conclusions, systemic effects on inhalation exposure cannot be excluded.

Public Risk Characterisation

The chemical 2-nitrophenol is not used in hair dyes in Australia (NICNAS, 2007). Use data for the USA indicate that the chemical may not be currently used in cosmetics. Public exposure to the chemical through cosmetics is, therefore, not expected.

Commercial use of the chemical in tobacco products can potentially be a source of public exposure.

In Australia, the chemical is regulated through its inclusion in Schedule 6 of the SUSMP under the group entry for 'NITROPHENOLS'. This measure is considered adequate to minimise any public risk resulting from any exposure to the chemical in products available to the public.

Occupational Risk Characterisation

During product formulation, oral, dermal, ocular and inhalation exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the adverse health effects associated with 2-nitrophenol, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see Recommendation section).

NICNAS Recommendation

Assessment of this chemical is considered to be sufficient, provided that the recommended amendments to the classification are adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2019).

Work Health and Safety

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Not Applicable	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

* Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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